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510(k) SUMMARY

Tumark Professional

Submitter:	Somatex Medical Technolgies GmbH Rheinstrasse 7d 14513 Teltow Germany Phone: +49 3328 3076 13 Fax: +49 3328 3076 99
Official Correspondent:	Susanne Raab Regulatory Affairs Consultant 1480 Cambridge Street Cambridge, MA 02139 Phone: 617 547 0628 Fax: 617 520 2136 e-mail: sbraab@comcast.net
Trade Name:	Tumark Professional
Common Name:	Tissue Site Marking System
Classification Name:	Radiographic Implantable Marker, 21 C.F.R. 878.4300
Regulatory Class:	II
Product Code:	NEU
Device Description:	The Tumark® is a sterile, single use, preloaded tissue site marking system consisting of a non-absorbable nickel-titanium marker, an introducer cannula and a plastic handheld applier with deployment mechanism. The introducer cannula which consists of stainless steel is designed with 1 cm depth marks, a beveled tip and an ultrasound enhancement on the distal end. The handle is equipped with a slide-button which allows for a one handed placement. A safety catch system prevents the slide-button

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from inadvertently moving forward and therefore prevents a premature deployment of the marker.

Intended Use:

The Tumark® Professional is intended to attach a marker to soft tissue at the surgical site during an open or a percutaneous procedure. It is indicated for use to radiographically and radiologically mark the surgical location in breasts following an open or percutaneous procedure. It is not indicated to be used with magnetic resonance imaging (MRI) techniques.

Substantial Equivalence:

The Tumark Professional is substantial equivalent to the ClipLoc Soft Tissue marker (the "ClipLoc") manufactured by MRI Devices Corporation (K033447) and the UltraClip Tissue Marker (the "UltraClip") manufactured by Inrad Inc. The Tumark and each of its predicate devices are intended to attach a marker to soft tissue at the surgical site during an open or a percutaneous procedure. All three devices are indicated for use to radiographically and radiologically mark the surgical location in breasts following an open or percutaneous procedure.

In addition, both the Tumark Professional and the predicate devices are similar in technology, design and material. Both the Tumark Professional and the predicate devices consist of the same primary components and the component materials of the proposed device and the predicate devices are substantially equivalent.

Based on the same intended Use and the similiarities in technolgy, design and materials the Tumark Professional is substantially equivalent to its predicate devices. The minor technological differences between the proposed device and the predicate devices do not raise new questions of safety and effectiveness.

Date Prepared:

February 19, 2008

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Somatex Medical Technologies GmbH
% Ms. Susanne Raab
1480 Cambridge Street
Cambridge, Massachusetts 02139

Re: K073095
Trade/Device Name: Tumark Professional
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: II
Product Code: NEU
Dated: February 23, 2008
Received: February 27, 2008

Dear Ms. Raab:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K073095

Indication for Use

510(k) Number (if known): K073095

Device Name: Tumark Professional

Indications for Use:

The Tumark® Professional is intended to attach a marker to soft tissue at the surgical site during an open or a percutaneous procedure.

It is indicated for use to radiographically and radiologically mark the surgical location in breasts following an open or percutaneous procedure. It is not indicated to be used with magnetic resonance imaging (MRI) techniques.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Division Sign-Off
Division of General, Restorative
and Neurological Devices

510(k) Number K073095